

NEW PATENT APPLICATION
PRELIMINARY AMENDMENT

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sample to be analyzed, and a labelled bioaffinity reactant B to cause said analyte and said labelled bioaffinity reactant B to specifically bind to said microparticles via the bioaffinity reactant A; and

- measuring [the] signal strength from [the] labelled bioaffinity reactant B bound to the microparticles to determine the analyte concentration in the sample, the improvement comprising:

- [using] contacting a predetermined amount of said sample, a predetermined number of uniformly sized microparticles coated with said bioaffinity reactant A and said labelled bioaffinity reactant B labelled with a luminescent label such that, after the specific binding of the analyte in the sample to said predetermined number of uniformly sized microparticles, each individual microparticle emits a signal strength that [is representative of] corresponds to the analyte concentration in the sample , and

- determining the analyte concentration in said sample by measuring the signal strength from [one or more] individual microparticles using a measuring means capable of reading the luminescence from single microparticles, the number of individual microparticles measured being the minimum number that will provide a statistically reliable measurement of the signal strength, and comparing said signal strength with a standardization curve, wherein said standardization curve is a mean of the signal strength

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of [a statistically reliable number of] said predetermined number of uniformly sized microparticles.

4. (Amended Three Times) The assay method according to claim 1, wherein an increasing sample volume is employed [in a non-competitive assay and in a competitive assay].

5. (Amended Three Times) The assay method according to claim 1, wherein a decreasing sample volume is used [in a non-competitive assay and in a competitive assay].

8. (Twice Amended) The assay method according to claim 1, wherein the assay comprises a competitive immunoassay, in which the labelled bioaffinity reactant B is an antigen, and the bioaffinity reactant A comprises an antibody for whose binding sites the labelled antigen and [the] an antigen of the analyte compete.

9. (Amended Three Times) The assay method according to claim 8, wherein the amount of said predetermined number of uniformly sized microparticles coated with the antibody A is [controlled] adjusted so that the lowest analyte concentration will result in the strongest signal.